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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,983	12/26/2001	Volker Nier	P67385US0	7797
7590 08/11/2004				
JACOBSON HOLMAN PROFESSIONAL LIMITED LIABILITY COMPANY 400 SEVENTH STREET, N.W. WASHINGTON, DC 20004			EXAMINER KREMER, MATTHEW J	
			ART UNIT 3736	PAPER NUMBER

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/025,983

Applicant(s)

NIER ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-19 and 31-33 is/are rejected.
- 7) ☒ Claim(s) 10 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/7/03; 3/28/02.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 3 and 8-10 are objected to because of the following informalities. Claim 3 recites the limitation "the complexing agent" in which there is insufficient antecedent basis. Appropriate correction is required. Claim 8 recites the limitation "the measured value" in line 4 in which there is insufficient antecedent basis. Claim 9 recites the limitation "the measured value" in line 4 in which there is insufficient antecedent basis. Claim 10 recites the limitation "the measured value" in line 3 in which there is insufficient antecedent basis. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,618,587 to Premoli et al. (Premoli). Premoli teaches the step of adding a protein complexing agent to the buffer to displace the calcium-protein complexing equilibrium towards the ionic form. (column 2, lines 61-66 of Premoli). In regard to claim 2, the added substance is a buffer solution of  $ZnCl_2$  and hydrochloric acid. (column 3, lines 50-56 of Premoli).

4. Claims 1-2 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,724,216 to Young et al. (Young). Young teaches the step of adding a releasing agent to release ionized calcium. (column 1, lines 29-40 of Young). In regard to claim 2, the added substance is a solution of formate salt and formic acid. (column 1, lines 29-40 of Young).

5. Claims 1-2 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 3,934,977 to Cleaver. Cleaver teaches the step of adding a buffer system that includes potassium hydrogen phthalate (a weak acid) to eliminate calcium binding by albumin. (column 2, lines 16-29 of Cleaver).

6. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 3,953,172 to Shapiro et al. (Shapiro). Shapiro teaches the step of determining the level of a substance in a fluid sample wherein complexing is interrupted by removing at least one reactant from the reaction environment. (Abstract and column 4, lines 5-44 of Shapiro).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4-9, 12-16, and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent Application Number 0330892 to Gamro AB (Gamro)(cited by Applicant) in view of U.S. Patent 5,780,438 to Gilchrist et al. (Gilchrist). Gamro teaches a dialyser means for controlling one or more parameters of the dialysis liquid. (Abstract of Gamro). Gamro teaches that the parameters can be calcium or potassium ions. (column 2, lines 44-52 of Gamro). Gamro does not teach the particulars of the dialysis liquid. Gilchrist teaches a dialysis liquid that would fulfill the requirements of providing a dialysis liquid as set forth in Gamro. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the dialysis liquid of Gilchrist in the method and system of Gamro since Gamro requires a dialysis liquid and Gilchrist teaches such a liquid. In regard to claim 4, Gilchrist teaches that the dialysis liquid includes citrate. (column 5, lines 31-36 of Gilchrist). In regards to claims 4-5 and 14, the combination teaches determining the Ca ion concentration, adjusting the dialysis fluid in response to the measurement (if necessary), which prevents the complexing of the Ca ions with the citrate before the next determination of the Ca ion concentration. In regard to claims 6 and 12, the adjusting of the dialysis fluid in the system would change the pH by either raising or lowering it. In regard to claims 7-9, the measurement is performed multiple times and is used to control the dialysis liquid. In regard to claim 13, the limitation "for the purpose of approximating the ion concentration of the dialysate to the ion concentration of the

blood” was not given patentable since the limitation merely states a purpose and not a method step.

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent Application Number 0330892 to Gamro AB (Gambro)(cited by Applicant) in view of U.S. Patent 5,780,438 to Gilchrist et al. (Gilchrist) as applied to claim 4, and further in view of Online Article “Patient Monitoring” by Togawa. The combination does not teach the use of an alarm but it is well known in the art that when physiological parameters are measured, an alarm is used when the parameter is outside a certain level to indicate an urgent condition for the patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the alarm of Togawa in the combination since an alarm indicates an urgent condition for the patient.

10. Claims 32-33 are is rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent Application Number 0330892 to Gamro AB (Gambro)(cited by Applicant) in view of U.S. Patent 5,780,438 to Gilchrist et al. (Gilchrist) as applied to claim 4, and further in view of U.S. Patent 3,912,455 to Lichtenstein. The combination teaches one or more ions can be determined. (column 2, lines 44-52 of Gambro). Lichtenstein teaches that magnesium ions are of interest in medical diagnosis. (column 2, lines 58-60 and column 7, lines 15-19 of Lichtenstein). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

determine magnesium ion concentrations as disclosed by Lichtenstein since the combination teaches other ion concentrations can be determined and Lichtenstein teaches one such ion concentration.

### ***Allowable Subject Matter***

11. Claims 10-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter. In regard to claim 10, the prior art does not teach or suggest the limitation "the measured value is determined by integration of an area of a response function defined by the ion concentration in the dialysate as a function of time" that is combined or combinable with the other limitations of claim 10. In regard to claim 11, the prior art does not teach or suggest the limitation "the pH is set to a range of pH = 2-3" that is combined or combinable with the other limitations of claim 11.

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 6,245,573 to Spillert teaches the measurement of clotting time by analyzing blood containing a calcium-binding anticoagulant such as citrate by adding a calcium salt to reverse the anticoagulant effect.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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